



SELECT AGENTS

Researchers Relieved by Final Biosecurity Rules

In a move that many university researchers welcome, the government has slightly relaxed new regulations aimed at beefing up security at biodefense research labs. The final rules on “possession, use, and transfer of select agents and toxins” do not dictate exactly what procedures labs should use but instead allow for flexibility—an approach scientific groups had recommended. At least one critic says the rules are a step backward, however.

The new rules on handling select agents—viruses, bacteria, and toxins that could be used to harm people, crops, or livestock—were required by a bioterror law passed in response to the 2001 anthrax letter attacks. Interim rules issued in December 2002 by the U.S. Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, and the U.S. Department of Agriculture (USDA) require registration with the government and background checks for anyone handling select agents, and they call for security procedures such as keeping agents in locked containers. The rules also require prior approval from the Department of Health and Human Services (HHS) for genetic engineering experiments that can make an agent more toxic or resistant to drugs. Violations can result in fines and criminal penalties.

When the interim regulations were first issued, scientists and universities protested that they were confusing, expensive—up to \$730,000 in start-up costs per lab—and could delay or impede research (*Science*, 21 February 2003, p. 1175).

The final rules, published in the 18 March *Federal Register*, should be more workable, says Emmett Barkley, who heads lab safety for the Howard Hughes Medical Institute in Chevy Chase, Maryland. One key change is that institutions will be allowed to tailor biosecurity plans to their own situations. The rules also now emphasize limiting “access” to select agents rather than securing a physical “area” or lab. This means biodefense researchers can share lab space with other researchers, and only those working with select agents have to undergo background checks. CDC now estimates that the total annual cost per lab will be \$15,300 to \$170,000.

Although the flexibility is good news, says Janet Shoemaker, public affairs director for



Handle with care. Final rule allows flexibility for labs dealing with agents such as anthrax.

the American Society for Microbiology (ASM) in Washington, D.C., universities will need more guidance. Depending on the agent, she says, “do you need guards 24 hours a day? Or are access cards and a locked freezer enough?” But helping institutions get up to speed shouldn’t be too arduous, she notes;

INFECTIOUS DISEASES

A Puzzling Outbreak of Marburg Disease

As many as 120 people may already have died in northern Angola from what could become the largest recorded outbreak of Marburg virus, a rare cousin of the Ebola virus that also causes hemorrhagic fever. Early this week, experts were rushing to the scene armed with diagnostic equipment, hoping to stanch the epidemic and learn more

only 417 labs are now registered to handle select agents, less than half the number predicted when the interim rule came out, and just 105 are academic institutions. Biodefense labs will receive further guidance from CDC and USDA this spring, and more this summer in the latest version of the CDC/National Institutes of Health’s biosafety manual.

Biodefense critic Richard Ebright, a microbiologist at Rutgers University in Piscataway, New Jersey, asserts that this relaxation of the rules increases the risk of accidents. In particular, he says, the focus on “access” rather than an entire lab “is especially egregious.”

Government officials left some issues unresolved—for instance, CDC declined to modify the select agent list, as ASM and others have requested. The government is also “studying” whether other experiments, such as engineering a vaccine-resistant virus or aerosolizing an agent, should require special approval from HHS.

—JOCELYN KAISER

about the mysterious disease, which has surfaced just six times over the past 4 decades.

To scientists, both the outbreak’s location and its manifestation are unusual. Marburg was known to occur only in Eastern and Central Africa, and “based on geography, you’d think this had to be Ebola,” says Thomas Geisbert of the U.S. Army Medical Research

Institute of Infectious Diseases (USAMRIID) in Fort Detrick, Maryland. According to the World Health Organization (WHO), about 75% of cases occurred in young children, also strange for a hemorrhagic fever virus, says Thomas Ksiazek of the U.S. Centers for Disease Control and Prevention in Atlanta, Georgia, the lab that first identified Marburg almost 2 weeks ago in samples shipped from Angola. Initial sequencing, however, does not suggest it’s an unusual strain, Ksiazek adds.

Marburg—which can cause fever, pains, diarrhea, coughing, nausea, and hemorrhaging—▶



Casualty. Italian pediatrician Maria Bonino (center), who worked in Uige province, has died, presumably from infection with the Marburg virus.

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